

## REMARKS

All of the method claims that were present in the application, Claims 1-7 and 19 and 20, have been canceled herewith. Claims 10-17 remain pending. Claims 10-14 are couched in means-plus-function language, and thus under 35 USC 112, paragraph 6, must be interpreted to be limited to the structure disclosed in the specification, or equivalents thereof. Given this proper interpretation of what these claims cover, it is respectfully submitted (for the reasons set forth below) that Claims 10-17 clearly distinguish over the prior art and should be allowable.

### I. Rejections Over the Prior Art:

In the Office Action noticed 07/10/09, yet another new grounds of rejection was presented. Under this new grounds of rejection, Claims 1, 10-11, and 16-17 were rejected under 35 U.S.C. 103(a) as being unpatentable (obvious) over Meadows et al, U.S. Patent No. 6,156,227. The Examiner stated that

"Meadows teaches a system for measuring and setting simulation levels in a spinal chord [sic] stimulation device. Threshold measurements may be taken by clinician programmer (column 5 lines 65-67) which are measure [sic] in terms of amplitudes. Although a different amplifier is not specified, such would be an obvious inclusion for measuring small amplitudes associated.[sic] Groups of electrodes may set in the form of a channel using the amplitudes from threshold levels to max levels. The pulse width may also be set in groups (column 35, lines 5-20). Thus each electrode will receive the same charge. To have set amplitude and pulse width to a value within the range above the lowest measured electrode threshold would be inherent of the device and method as a result of the choice of range."

Office Action noticed 07/10/09, Page 2.

The rejection of method Claim 1 is moot because Claim 1 has been canceled. With respect to Claims 10-11 and 16-17, Applicant respectfully submits that the Examiner has mischaracterized Meadows and/or has confused the type of measurements disclosed in Meadows versus the type of measurements called for in the claim. Contrary to the Examiner's characterization of Meadows, Meadows does not teach, or suggest, "means for recording when an applied stimulus elicits an ECAP to occur," which is what Claim 10 (and all the claims that depend therefrom) requires. The Examiner has apparently confused this "means for recording when an applied stimulus elicits an ECAP" to be the same as measuring stimulation levels. It is not. The means for recording when an applied stimulus elicits an ECAP to occur is what requires the use of a differential amplifier in order to record the very low amplitude signals that evidence the occurrence of the ECAP. Once the ECAP occurrence has been sensed, or recorded, then the system can note what amplitude of stimulus was used when the ECAP occurred.

Thus, under the claimed structure, and pursuant to 35 U.S.C. 112, sixth paragraph, a differential amplifier, or equivalent, must be used to determine the occurrence of the ECAP. When the ECAP occurs, the amplitude of the stimulus that evoked the ECAP (which amplitude is already known) is flagged or tagged as the stimulus amplitude for which a stimulus charge is determined. Then, the system sets the program levels of the stimuli applied by during its operation to stimuli having approximately the same charge as the charge that elicited the ECAP.

As thus claimed, this is a very different approach for setting the program levels of the applied stimuli than anything that is shown or suggested in Meadows. The claimed structure requires making a determination, or measurement, of the occurrence of an electrically evoked action potential (ECAP). Meadows does not measure an ECAP. There is no need for an ECAP measurement or recording in the SCS system described in Meadows. All that Meadows teaches is what is done in any spinal cord stimulation (SCS) system, i.e., a stimulus pulse is applied to a selected location along the spinal cord so as to cause a tingling sensation, or parasthesia, to be sensed by the patient at a site that corresponds to where the patient feels pain. The amplitude of the stimulus pulse may

then be adjusted until the paresthesia sensed by the patient is sufficient to successfully block out the pain. Any measurements that are made during such a process are *subjective* measurements, made by getting responses or feedback from the patient as to what the patient feels in response to the stimulus. There are no objective measurements that provide an indication of when an electrically evoked action potential (ECAP) occurs.

Thus, when Meadows states that the "CP system include(s) . . . the ability to take stimulus threshold measurements" (Col. 5, lines 65-67) it means that it can measure, i.e., record, at what stimulus level the patient indicates a paresthesia is first felt. It does not mean, nor does it suggest, that the system uses a differential amplifier, or equivalent circuitry, to measure a very small and difficult-to-sense ECAP signal as is required by Claim 10 of the instant application.

The subjective measurements used in a spinal cord stimulation system, such as those described in Meadows, involve recording the stimulus levels corresponding to when a threshold or desired stimulus level is achieved based on subjective feedback from the patient as to when the sensed paresthesia or tingling feels just right. These types of measurements are totally irrelevant and unrelated to an objective measurement of the ECAP signal. Hence, the teachings of Meadows just do not fill the gap regarding the differences between what is claimed in the instant application and what Meadows teaches, shows or suggests. Said another way, SCS systems are essentially open-loop systems that set the stimulus level as a function of subjective measurements provided by the patient in response to an iterative process of adjusting the stimulus level. In contrast, a neural stimulation system of the type claimed in Claim 10 uses a type of closed loop system wherein an objective measurement is made of the occurrence of the ECAP signal, and that measurement is then used to determine the charge level corresponding to the stimulus that evoked that measured ECAP, and then that charge level is used to set level of the stimulus that should be applied. There is nothing *subjective* about this approach, i.e., it is not dependent upon receiving feedback from the patient as to what the patient feels or does not feel. The difference between the two approaches is huge, and one approach does not suggest the other. Thus, it is respectfully submitted that a *prima facie*

case of obviousness has not been established, and that the rejection of Claim 10, and the claims that are dependent therefrom, should be withdrawn.

The Examiner further rejected Claims 2-7, 12-15 and 19-20 under 35 U.S.C. 103(a) as being unpatentable (obvious) over Meadows et al U.S. Pat. No. 6,156,227, as applied to claims 1, 10-11, 16-17, in view of WO 01/43818 or Frank et al "Estimation of Psychophysical Levels Using the Electrical evoked compound action potential measured with Neural Response Telemetry Capabilities of Cochlear Corporation's C124M Device." The Examiner stated that the dependent claims "differ from Meadows in the mapping and determination of threshold levels using multiple stimuli. To have modified the Meadows application to include such techniques for determining the threshold levels that Meadows seeks would have been obvious."

This rejection of method Claims 2-7 and 19-20 is now moot in view of the cancellation of the method claims. With respect to apparatus claims 12-15, these claims should be allowable for at least the same reason that independent Claim 10 is allowable, i.e., as indicated above, Meadows doesn't teach or suggest the using the claimed structure to measure the occurrence of ECAP signals, determining charge level, and using the charge level to determine the appropriate stimulus level that should be applied.

Further, the rejection as worded does not establish a *prima facie* case of obviousness because the rejection statement is a mere conclusion. To properly arrive at a finding of obviousness, there must be a careful and thoughtful analysis as to what the level of skill is in the relevant art, what the differences are between the claimed invention and the teachings of the prior art, and why those differences would have been obvious to a person of skill in the art. To simply conclude that the difference between Applicant's dependent claims and Meadows -- the mapping and determination of threshold levels using multiple stimuli-- is obvious without providing an appropriate obviousness analysis shows either a lack of understanding as to what the invention is, and/or evidences the application of hindsight. The invention, as set forth in Claim 10, and the claims that depend from Claim 10, sets forth novel and nonobvious structure that uses objectively measured ECAP levels to identify charge levels associated with stimuli that produced the measured ECAP levels, and then maps those charge levels to charge levels of the

stimulus to be applied in a way that is totally unrelated to any approach or technique shown or suggested in Meadows, and hence the rejection cannot stand and should be withdrawn.

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In view of the above, Applicant respectfully requests that this Amendment be entered, that the rejection of Claims 10-17 be withdrawn, and that a Notice of Allowance issue. Should the Examiner disagree, and not be persuaded by the above remarks, then it is respectfully submitted that this Amendment must still be entered so that the case will be in better form for appeal.

Respectfully submitted,

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